## REMARKS

Claims 1-3, 5, 13, 15-18, 20-23, 32-36 and 39-46 are currently pending. Claims 4, 11, 12, 14, 19 and 24-31 were previously cancelled and claims 6-10, 37 and 38 are currently cancelled. Claims 1, 2, 13, 17, 21, 22 and 32-36 are currently amended. New claims 39-46 are added. No new matter is added.

### I. Examiner Interview

Applicants would like to thank Examiner DeSanto and Supervisory Examiner Lucchesi for the interview with Jocelyn D. Ram (54,898) on April 15, 2008. In this interview, the Examiners agreed that the Dye reference does not have "a distal opening having a projected area that is smaller than the cross-sectional area of a section of the shaft proximal to the distal end of the shaft," as recited in all the independent claims, thus this rejection will be withdrawn. The Examiner agreed that Magasi does not anticipate claim 34 or claim 37. The Examiner agreed that claim 36 as amended herein is not anticipated by Magasi. The Examiner also agreed that method claims 13, 17 and 22 as amended herein are not anticipated by Magasi.

### II. 35 USC 112, 1st Paragraph Rejection

Claims 6-10 stand rejected as allegedly failing to comply with the written description requirement. Claims 6-10 are cancelled, thus this rejection is moot.

### III. 35 USC 102 Rejection - Claims 1, 2, 6-10 and 32-38 over Magasi

Claims 1, 2, 6-10 and 32-38 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by US Patent No. 4,826,492 to Magasi ("Magasi"). Applicants respectfully traverse this rejection because Magasi does not describe each and every element of the claims.

### A. Independent Claim 1

Magasi does not describe a "a catheter or syringe having a distal portion, and a needle comprising during use: a shaft having a distal end defining a distal opening and having a longitudinal axis extending through the distal opening, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft, wherein the distal-most end is a curvilinear blunt tip" as recited in claim 1. The

Examiner relies on Figure 6 as the basis for his rejection. As Applicants have argued before, Figure 6 shows an intermediate product, and not an end product (probe 10). Figure 6 is described as "illustrating the method of *manufacture* of the probe of FIG. 1" (col 3, lines 67-68). Thus, an intermediate product cannot be construed as being the form of the needle *during use*, since this would go against the teaching of the reference. Furthermore, Magasi did not intend for the intermediate product to be attached to a catheter or syringe. Rather, one or ordinary skill in the art would use the end product in Magasi to puncture tissue.

Furthermore, with respect to Figures 1 and 2, the distal-most end is not a curvilinear blunt tip, as claimed. The puncturing tip 2 in the final product is shown as a sharp point in Figures 1 and 2, as opposed to the rounded end shown in the intermediate product of Figure 6. Thus, Magasi does not disclose all the limitations of independent claim 1.

**B. Independent Claim 34**

With respect to independent claim 34, Magasi does not describe a "a catheter or syringe having a distal portion, and a needle attached to the distal portion, the needle comprising during use: a shaft having a distal end comprising a first surface indented towards a second surface to define a *distal opening having U-shape* when viewed from the distal end, the shaft having a longitudinal axis extending through the distal opening, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft." Although Figure 6 shows a generally U-shape, as discussed before, Figure 6 shows an intermediate manufacturing step and thus cannot be interpreted as being the form of the needle "during use". Furthermore, Magasi did not intend for the intermediate product to be attached to a catheter or syringe. The final product shown in Figures 1 and 2 clearly does not have a U-shaped distal opening. Thus, Magasi does not disclose all the limitations of independent claim 34, as the Examiner agreed in the Interview.

**C. Independent Claim 36**

With respect to independent claim 36, Magasi also does not describe "a catheter or syringe having a distal portion, and a needle attached to the distal portion, the needle comprising during use: a shaft having a distal end defining a distal opening and having a longitudinal axis extending through the distal opening, the distal end comprising a first surface only indented

towards a second surface to form a concavity on an outer portion of the first surface, the second surface being parallel to the longitudinal axis of the shaft, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft." Although Figure 6 does show a first surface indented towards a second surface, as discussed before, Figure 6 shows an intermediate manufacturing step and thus cannot be interpreted as being the form of the needle "during use". Furthermore, Magasi did not intend for the intermediate product to be attached to a catheter or syringe. The final product shown in Figures 1 and 2 has a displacement surface 4, however this surface 4 does not have a concavity on an outer portion thereof, as the Examiner agreed in the Interview. Thus, Magasi does not disclose all the limitations of independent claim 36.

## IV. 35 USC 102 Rejection - Claims 34-38 over Dye

Claims 34-38 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by US Patent No. 3,788,320 to Dye ("Dye"). However, Dye does not describe all the limitations of claims 34 and 36 (and all claims dependent therefrom). In the Examiner Interview, the Examiners agreed that the pending claims would overcome the Dye reference.

Dye describes a spinal needle comprising a hollow outer needle 12 and a stylet removably insertable therein that has a generally closed piercing end 32. Dye describes the face 40, face 42, and heel face 62 of stylet 22 is inserted into needle 12 form a closed tip, thus there are no distal openings (column 2, lines 49-60). In the Final Office Action, the Examiner cites column 3, lines 39-43 as Dye's disclosure of a distal opening, which states that when the stylet 22 is removed, the outer needle 12 has a distal opening. In the Advisory Action, the Examiner states, "Once the stylet is removed there is a distal opening and this opening will have a shape that is the same when the stylet is in the needle." Applicants agree that there will be an distal opening when the stylet is removed, however this opening does not have the form as claimed. It is unclear what the Examiner means by the phrase, "this opening will have a shape that is the same when the stylet is in the needle." There is no argument that the opening will change shape depending on whether the stylet is in the opening or not.

When there is no stylet in the needle 12, the locations where 40, 42 and 62 are shown in Figure 4 are open. Furthermore, there are no indented surfaces, but rather the needle 12 is manufactured by cutting a cylinder at different angles. Dye states that the needle has a uniform

cylindrical bore 18 (col 2, lines 29-30), thus there is no first surface indented toward a second surface (claims 34 and 36), as claimed. Figures 5-7 further show cross-sectional views that confirm that the needle remains cylindrical even at the distal end. Furthermore, with respect to claim 34, Dye fails to disclose a distal opening having a U-shape when viewed from the distal end. Additionally, Dye does not disclose the limitation of the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft (claims 34 and 36). No sort of cuts on a cylinder can change the projected area of the opening.

For at least these reasons, Applicants submit that Dye does not anticipate claims 34-38 and Applicants request withdrawal of this rejection.

**V. 35 USC 103 Rejection - Claims 3, 5 and 12 over Magasi in view of Alchas**

Claims 3, 5 and 12 (which depend from claim 1) stand rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious over Magasi in view of US Patent No. 4,537,593 to Alchas ("Alchas"). Magasi does not describe all the limitations of claim 1, as discussed above, and Alchas cannot make up for these deficiencies. Alchas does not describe a catheter, and further does not describe a needle having a distal-most end that is a curvilinear blunt tip. The tip of Alchas is a closed pointed tip. Alchas states that the *closed planar portion* 31 "terminates at a straight edge 32 lying at an angle to longitudinal axis 34" (see col. 5, lines 42-46). Further, Alchas states that "flat portion 31 includes a tapered portion 35 which is tapered toward straight edge 32 in a razor-like fashion" (see col. 5, lines 53-55). For at least these reasons, Applicants submit that claim 3 is not rendered obvious over Magasi in view of Alchas, and Applicants request withdrawal of this rejection. Applicants note that claims 5 and 12 have been cancelled, thus this rejection is moot.

**VI. 35 USC 103 Rejection - Claims 11 and 13-16 over Magasi in view of Altman**

Claims 11 and 13-16 stand rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious over US Patent No. 6,346,099 to Altman ("Altman"). It is noted that the Examiner does not state that the claims are rejected over Magasi in view of Altman, however the Examiner's

discussion appears to indicate such. Claims 11 and 14 were previously cancelled, thus this rejection is moot.

Magasi does not describe all the limitations of independent claim 13, and all claims dependent therefrom. Claim 13 recites, "A method of delivering a therapeutic agent to a target site of a body comprising: providing a drug delivery device comprising: a non-coring needle having a distal end defining a distal opening and having a longitudinal axis extending through the distal opening, the distal end comprising a first surface only indented towards a second surface to form a concavity on an outer portion of the first surface, the second surface being parallel to the longitudinal axis of the shaft, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft; puncturing a body tissue with the non-coring needle tip; and delivering the therapeutic agent through the non-coring needle to a target site of a body."

Magasi does not describe providing a non-coring needle as claimed, and puncturing a body tissue with the non-coring needle. The needle that the Examiner cites in Magasi is that of Figure 6, which is an intermediate product. This needle form cannot be used to puncture tissue, since one of ordinary skill would instead use the end product of Magasi for this purpose. These deficiencies cannot be cured by Altman.

Altman describes a catheter drug delivery system, having a stainless steel needle 312 with a penetrating tip 316 for delivering a therapeutic into the myocardium. However, Altman does not disclose a non-coring needle tip as claimed. The needle of Altman is sharp, not a curvilinear blunt tip. Furthermore, the distal opening of Altman has a projected area that is the same as a cross-sectional area of a section of the shaft proximal to the distal end of the shaft.

Furthermore, there is no teaching, suggestion, or motivation to use the intermediate product of Magasi in Altman's method for delivering a therapeutic agent to a target site of the body. For at least this reason, Applicants submit that claims 13, 15 and 16 are not rendered obvious over Magasi in view of Altman. As such, Applicants request withdrawal of this rejection.

**VII. 35 USC 103 Rejection - Claims 17-20 over Magasi in view of Luther**

Claims 17-20 stand rejected as being allegedly rendered obvious over Magasi in view of US Patent No. 5,873,864 to Luther ("Luther"). Claim 19 was previously cancelled, thus this rejection is moot.

Magasi does not describe all the limitations of independent claim 17, and all claims dependent therefrom. Claim 17 recites, "A method of accessing a drug delivery port comprising: providing a drug delivery device comprising: a non-coring needle having a distal end defining a distal opening and having a longitudinal axis extending through the distal opening, the distal end comprising a first surface only indented towards a second surface to form a concavity on an outer portion of the first surface, the second surface being parallel to the longitudinal axis of the shaft, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft; and inserting the needle of the drug delivery device into a drug delivery port to access the drug delivery port."

Magasi does not describe providing a non-coring needle as claimed, and accessing a drug delivery port with the needle. The needle that the Examiner cites in Magasi is that of Figure 6, which is an intermediate product. This needle cannot be used to access a drug delivery port, since one of ordinary skill would instead use the end product of Magasi for this purpose. These deficiencies cannot be cured by Luther.

Luther describes a method of inserting a needle into a drug delivery port, having a beveled tip that is designed for non-coring. Additionally, the distal opening at tip 48 in Luther has a projected area that is the same as a cross-sectional area of a section of the shaft proximal to the distal end of the shaft. Furthermore, in Luther the longitudinal axis does not extend through the distal opening.

Furthermore, there would be no motivation to use the intermediate product of Magasi in Luther's method of accessing a drug delivery port. For at least this reason, Applicants submit that claims 17, 18 and 20 are not rendered obvious by the combination of Magasi and Luther. As such, Applicants request withdrawal of this rejection.

**VIII. 35 USC 103 Rejection - Claim 21 over Magasi in view of Gross**

Claim 21, which now depends from claim 13, stands rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious over Magasi in view of US Patent No. 5,843,048 to Gross ("Gross"). As stated above, Magasi does not describe all the limitations of claim 13. Gross does not make up for these deficiencies.

Magasi does not describe providing a non-coring needle as claimed, and puncturing a body tissue with the non-coring needle. The needle that the Examiner cites in Magasi is that of

Figure 6, which is an intermediate product. This needle cannot be used to puncture tissue, since one of ordinary skill would instead use the end product of Magasi for this purpose. These deficiencies cannot be cured by Gross.

Gross describes an epidural needle having a "blunted tip" (40) through which a catheter can be inserted. In Gross, the longitudinal axis does not extend through the distal opening.

Furthermore, there is no teaching, suggestion, or motivation to use the intermediate product of Magasi in Gross' method for delivering an epidural to a spinal column. For at least these reasons, Applicants submit that claim 21 is not rendered obvious over Magasi in view of Gross. Accordingly, Applicants request withdrawal of this rejection.

**VIII. 35 USC 103 Rejection - Claims 22 and 23 over Magasi in view of Johnson**

Claims 22 and 23 stand rejected as being allegedly rendered obvious over Magasi in view of US Patent No. 5,817,052 to Johnson ("Johnson"). Magasi does not describe all the limitations of claim 22, and all claims dependent therefrom. Claim 22 recites, "A method of collecting a fluid sample from a body comprising: providing a drug delivery device comprising: a non-coring needle having a distal end defining a distal opening and having a longitudinal axis extending through the distal opening, the distal end comprising a first surface only indented towards a second surface to form a concavity on an outer portion of the first surface, the second surface being parallel to the longitudinal axis of the shaft, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft; puncturing a body tissue with the non-coring needle; inserting the needle into a fluid containment site of a body; and creating a vacuum in the drug delivery device to collect a fluid sample from the fluid containment site of the body."

Magasi does not describe providing a non-coring needle as claimed, and puncturing a body tissue with the non-coring needle. The needle that the Examiner cites in Magasi is that of Figure 6, which is an intermediate product. This needle cannot be used to access a drug delivery port, since one of ordinary skill would instead use the end product of Magasi for this purpose. These deficiencies cannot be cured by Johnson.

Johnson describes an apparatus for intraosseous infusion or aspiration, which has a tip that is specifically designed to penetrate bone. Johnson does not describe a curvilinear blunt tip,

but rather describes bone penetrating means 50. Additionally, Johnson does not disclose a distal opening, but instead has a side port for injecting/suctioning fluids.

Furthermore, there is no teaching, suggestion, or motivation to use the intermediate product of Magasi in Johnson's method for aspirating bone marrow. For at least this reason, Applicants submit that claims 22 and 23 are not rendered obvious by the combination of Magasi and Johnson. As such, Applicants request withdrawal of this rejection.

## CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,
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